REMARKS

Claims 1-9 and 11.20 are pending in the application.

Claims 1, 3, 709 and 11-18 have been amended to more succinctly claim what it is that the Applicant regards as the invention.

Claim 10 is cancelled from the application without prejudice.

No new matter has been added to the application by way of these specification and claim amendments.

I. THE SPECIFICATION

The examiner raised several objections to the specification.

The examiner's objections are overcome by amending the specification above to overcome the objections.

II. THE CLAIM OBJECTIONS

The examiner raised objections to claims 3 and 11-18 in the Office Action.

The objections are overcome by:

- Canceling the term "as herein defined" from claims 3 and 12.
- Amending claims 11-18 to start with the word "An".

III. TRAVERSE OF THE ANTICIPATION REJECTIONS

A. The McKeown Anticipation Rejection

The examiner rejected claims 1, 2-4, 10 and 12-13 for being anticipated by the McKeown et al. article. (McKeown). Applicant has amended independent claim 1 above to further clarify the nature of the invention claimed. The amendments cause independent claim 1 and claims 2-4, 10 and 12-13 which depend directly or indirectly upon claim 1 to be novel over McKeown.

Claim 1 is now restricted *inter alia* to:

> A method for non-invasive of monitoring electrical muscular activity which is at least partially due to a non-stationary muscular source,
>
> a blind signal separation technique, and

the signal electrodes being localised sufficiently such that their muscular signal contributions simulate a single muscular source to the blind signal separation technique despite at least partial non-stationarity of the muscular source.

McKeown does not disclose the elements of claim 1 as amended. In particular, there is no disclosure in McKeown of a method of non-invasively monitoring electrical muscular activity which is at least partly due to a non-stationary muscular source because the independent component analysis (ICA) algorithm used by McKeown does not work for a non-stationary source. The reason McKeown's ICA algorithm does not work for a non-stationary source is described in Applicant's specification at page 16 lines 30-33 If two different electrodes receive respective versions of a non-stationary uterine signal, and one of these versions is delayed relative to the other, ICA treats the delayed version as a different signal to the undelayed version. For this reason, ICA cannot separate a non-stationary source correctly from other signals. This shortcoming with ICA is further discussed in Applicant's specification at page 16 lines 14-17 and at page 1 lines 17-18 of WO 03/073612 which is cited in Applicant's specification at page 17 line 13.

The McKeown ICA shortcoming is also exemplified in Applicant's specification at page 23 lines 8-34 and illustrated in Figures 6 and 7 which show uterine activity signals before and after ICA. Because the uterine activity is from a non-stationary source, in Figure 7 at least seven signals (instead of one) derived using ICA show a uterine contribution. ICA, therefore, completely fails to separate the uterine activity because it is from a non-stationary source. If the uterine signal contribution had been from a stationary source, the ICA signal separation process would have worked effectively, and the uterine signal contribution would have appeared on only one signal in Figure 7 instead of on at least seven out of twelve signals. Furthermore, since the uterine signal contribution gives rise to at least seven signals in Figure 7, it is being treated by ICA as at least seven different sources. Consequently, since there are other sources (e.g. uterine activity and fetal ECG), Figure 7 indicates ICA may be detecting more sources than there are electrodes, which is contrary to claim 1 and does not allow a (BSS) technique to work.

In this connection Figure 1 of McKeown shows *inter alia* two scatter plots, one with cross-talk and one from which cross-talk has been eliminated by ICA. Cross-talk means signal mixing, e.g. one electrode picking up a mixture of two or more different signals. ICA is a BSS technique for separating or "unmixing" mixed signals to reduce or eliminate cross-talk.

However, as discussed above, ICA only works for stationary sources. It is very clear, therefore, that McKeown only deals with stationary sources, because McKeown's two scatter plots illustrating ICA removing cross-talk are characteristic of stationary sources.

An important application of the claimed invention is separating the maternal uterine signal from the fetal ECG in order to monitor the progress of labour and fetal cardiac status simultaneously. The maternal uterine signal is a non-stationary source and the fetal ECG is a stationary source. As indicated in Applicant's specification at page 16 lines 26-28, a contraction propagates slowly down the uterus at ~2cm/sec, so a contraction initiated from the top of the uterus in the vicinity of electrodes 10 to 12 could take ~12 sec to move down ~24cm to the level of lowermost electrodes 1 and 2 in Figure 4. This demonstrates that a contraction is a non-stationary source, because it moves a long distance relative to the electrodes 1 to 12, across their full downward extent with respect to an upright patient. In McKeown, there is no comparable movement of a signal source. Electrode placement is given in McKeown page 48 right-hand column line 8 to page 49 left-hand column line 5. Electrodes are placed on the scalp and on individual muscles. For the purposes of signal separation using ICA these sources are stationary sources, not non-stationary sources.

Applicant's inventor discovered that, surprisingly having regard to Figures 6 and 7, it is actually possible to carry out signal separation for a non-stationary source using a signal separation process suitable only for stationary sources. This discovery is subject to the proviso that the electrodes monitoring the non-stationary source are sufficiently localised to obtain signal contributions simulating a stationary source. As described in Applicant's specification at page 17 lines 18-22, electrodes 7, 8 and 10 to 12 have like time delays for receipt of signals from the non-stationary uterine source, which causes the source to appear to be stationary as far as the signal separation process is concerned. This feature of independent claim 1 is not disclosed by McKeown and Applicant's invention is therefore novel. Moreover, claims 2-4 are also novel over McKeown at least by virtue of their dependency upon independent claim 1.

B. The Rosenburg Anticipation Rejection

The examiner rejected claims 1-2, 6, 10-11, and 15 under 35 U.S.C. 102(b) as allegedly being anticipated by Rosenburg. It is the examiner's position that Rosenburg discloses all the elements of independent claim 1 in particular.

Rosenburg discloses a technique which quite different to Applicant's invention. Indeed, Rosenburg does not disclose the elements of claim 1 as amended, because *inter alia* Rosenburg does not disclose blind signal separation. There is no disclosure in Rosenburg whatsoever regarding separating individual signals out of mixtures of signals, the mixtures being received by each individual electrode. All Rosenburg discloses is taking individual electrode signals and processing them separately. The portion of Rosenburg cited by the examiner for disclosing signal separation - Column 9 line 44 - Column 10 line 6 – actually discloses an electrode signal (which is a mixture of signals) that is amplified and displayed individually. The cited excerpt does not disclose the application of a BSS process in combination with other electrode signals. Therefore, the Rosenburg disclosure would be quite useless for the important application of Applicant's invention regarding separating uterine activity and fetal ECG (or EKG). For at least this reason, independent claim 1 is novel over Rosenburg. Claims 2 and 6 are also novel over Rosenburg at least by virtue of their dependency upon independent claim 1.

C. The Garfield Anticipation Rejection

The examiner rejects claims 1, 7-10, and 16-18 under 35 U.S.C. 102 (b) as allegedly being anticipated by Garfield et al. (Garfield).

Like Rosenburg, Garfield discloses a technique which is quite different from Applicant's claimed invention. Garfield does not disclose all of the elements of claim 1 as amended, because *inter alia* Garfield does not disclose blind signal separation. There is no disclosure in Garfield whatsoever regarding separating mixtures of signals received by individual electrodes. All Garfield discloses is taking individual electrode signals and processing them without using blind signal separation. The examiner's cited filters/amplifiers 20 and computer 22 in Garfield Figure 1 do not separate signals but instead signal frequencies. Clearly each signal can have a range of frequencies and will be scattered over a series of frequency bins each consequently containing a mixture of contributions from multiple signals. (*See, e.g.*, frequency bins 25 in Figure 2). What is shown and discussed in Garfield is not blind signal separation, which separates signals themselves not frequency components of multiple mixed signals. Like Rosenburg, the Garfield disclosure would be quite useless for Applicant's important application of separating uterine activity and fetal ECG. For at least this reason, independent claim 1 is novel over Garfield. Claims 7-9 are also novel over Garfield at least by virtue of their dependency upon independent claim 1.

Claim 7 is independently novel and patentable. It is the examiner's position that Garfield discloses placing first and second sets of signal electrodes upon the patient's skin, the first set being localised sufficiently to simulate a single source to the signal separation technique, and the second set not being so localised with the first set used to monitor non-stationary muscular activity and both sets used to monitor stationary muscular activity. The basis for the examiner's rejection of claim 7 is faulty on several grounds.

a) The Garfield extract cited by the examiner in support of the claim 7 rejection (page 35 line 22 - page 36 line 8) does not disclose two sets of signal electrodes upon the patient's skin, one set being localised sufficiently to simulate a single source and the second set not. The cited excerpt of Garfield merely discloses one set of electrodes, "a multi-electrode array" at page 35 line 23 and as shown in Figure 10 and not one localised set and one unlocalised set;

b) Garfield does not disclose the use of a blind signal separation technique as per claim 1 from which claim 7 depends; and

c) Garfield does not disclose using the first set of signal electrodes for monitoring non-stationary muscular activity and using both sets of signal electrodes for monitoring stationary muscular activity. Garfield merely discloses using all the electrode signals in the same way – see page 35 lines 30-32.

Claim 7 is novel and patentable for each of these reasons.

D. Claims 11-13 And 15-19 Are Novel And Patentable

The examiner rejected claim 10 under 35 U.S.C. 102(b) as allegedly being anticipated by McKeown. Claim 10 is deleted above and replaced by new independent claim 19, with respect to which the rejection of claim 10 will be discussed.

Claim 19 incorporates limitations similar to claim 7. Claim 19 relates to apparatuses for monitoring activity of two muscular sources, one of which is non-stationary and the other stationary. There are claimed two sets of electrodes. One set of electrodes is for use in monitoring non-stationary muscular activity and both sets of electrodes are for use in monitoring stationary muscular activity. Electrodes in the one set are localisable to provide for non-stationary muscular activity to appear stationary, so they must not be too large or too numerous to defeat this requirement. Claim 19 includes computer apparatus programmed to implement a blind signal separation technique suitable for separating stationary signals: this technique is for processing (i) digital signals derived via one set of electrodes to separate the non-stationary source, and (ii) digital signals derived via both sets of electrodes to separate the stationary source. Independent claim 19 is not anticipated because McKeown does not disclose two sets of

electrodes per patient, and does not work for non-stationary muscular activity in any event for reasons given above in Section III(A) with respect to claim 1.

Claim 10 is also rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Rosenburg and Garfield. Claim 19 is novel and patentable over both Rosenburg and Garfield for the reasons given above regarding McKeown and also because neither reference discloses blind signal separation. Claims 11-13 and 15-18, which depend upon claim 19, are novel at least by virtue of their dependency.

IV. TRAVERSE OF THE OBVIOUSNESS REJECTION

The examiner rejected claims 5 and 14 for being obvious over McKeown in view of the Cichocki et al. Article. Claim 1 is novel and patentable over McKeown for the reasons recited in Section III(A) above. Therefore, claims 5 and 14 are patentable by virtue of their dependence on allowable claim 1.

Claim 5 is further non-obvious because Cichocki et al. does not disclose applying ICA to processing data arranged in successive overlapping blocks, and applying a correlation scheme to re-order independent sources and correct for signal swapping as the examiner maintains. The pages the examiner relies upon for supplying this teaching - i.e. pages V-78 and V-79 "2. Linear Demixing State Space Models"; the Cichocki et al Abstract and the Introduction on page V78 do not support the examiner's obviousness position. Indeed, there appears to be no reference whatsoever in Cichocki et al. to processing data arranged in successive overlapping blocks or to a correlation scheme to re-order independent sources and correct for signal swapping. For at least this reason, claim 5 is independently patentable.

CONCLUSION

The examiner's specification and claim objections and rejections are overcome or they are traversed for at least the reasons discussed above. Favorable reconsideration and allowance of all pending application claims is, therefore, courteously solicited.

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